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December 13, 1999

The Honorable Tom Bliley Chairman Committee on Commerce 2125 Rayburn House Office Building Washington, DC 20515

Dear Chairman Bliley:

In a November 23, 1999, letter to the American Hospital Association (AHA), you asked for the AHA's views on a variety of matters related to the National Practitioner Data Bank (NPDB). We appreciate the opportunity to share those views with you.

The AHA supports the goals of the Health Care Quality Improvement Act, under which the NPDB was created. The act recognizes the importance of encouraging and supporting effective professional peer review to help protect consumers from incompetent or dangerous performance by practitioners. The AHA and its members are engaged in a range of activities to help hospitals and health systems deliver the highest quality care. None is more important than the peer review and quality assurance activities that occur every day in hospitals across the country.

Hospitals and other health care organizations hold a unique position in today's society. Their primary focus is the care of individuals and their families. The hospital board and leadership, in conjunction with the clinical staff, must develop and implement comprehensive systems and procedures to safeguard and enhance the quality of patient care and services. They also actively monitor and immediately act upon, where appropriate, the knowledge gained from those systems and procedures so that patient and staff safety is ensured and patient care improved.

Every health care organization must provide a safe environment, and continually strive to ensure the safe delivery of health care services. The organization must also ensure that the workforce, including all clinical staff affiliated with the organization, is competent, adequately credentialed and trained.

The recent Institute of Medicine report has brought a sharp focus to the issue of medical error. The AHA and its members have launched an initiative to address medication error, one of the most common medical errors. Our initiative includes education, such as providing "successful practices" that can help reduce errors, and partnerships with other

Washington, DC Center for Public Affairs
Chicago, Illinois Center for Health Care Leadership

Liberty Place, Suite 700 325 Seventh Street, N.W. Washington, DC 20004-2802 (202) 638-1100

organizations that have been leaders in addressing this issue. Across the nation, hospitals are taking a comprehensive look at their ability to prevent medication errors and make improvements where needed.

To make this effort a success, we need an environment that supports the acknowledgment of error, not one that threatens punishment or fear of legal prosecution for doctors, nurses, and other caregivers who step forward after an unfortunate mistake is made.

We remind you of this because the NPDB does not exist in a vacuum. Issues of patient safety and care improvement are now, and must continue to be, addressed at the local level. AHA believes that the NPDB should not inhibit effective peer review activities.

The following is in response to your specific questions.

1. Is there underreporting to the NPDB?

Hospitals take seriously their legal reporting obligations to the NPDB. The AHA is not aware of any data which documents that hospitals are not meeting these obligations. Questions about potential noncompliance appear to be based on anecdotal information and studies that use the level of hospital reporting to suggest that NPDB requirements are not being met. While a number of hospitals have been noted as not reporting to the NPDB, that does not mean that they are not effectively overseeing health care practitioners. The studies we are aware of continue to measure current reporting against what appears to have been, at best, projections of future reporting at the time the NPDB was created.

There is no reason to assume that the numbers of adverse actions have remained constant since before the inception of the NPDB. It is also natural that the threshold for reporting to the NPDB may have become a benchmark for addressing more serious situations. Reporting and being reported are viewed as serious actions. Alternative interventions include the use of supervision, requiring medical education, and short-term limitations on privileges. Hospitals are, of course, accountable for the care within the facility and bear legal responsibility.

The potential consequences for hospitals that are involved in adverse actions are significant. Notwithstanding the immunity provision of the statute, hospitals continue to face litigation related to adverse actions. At the same time they are subject to sanctions from the NPDB for failing to report.

2. Should there be expanded reporting regarding disciplinary actions?

The AHA is concerned that reporting to the NPDB not create a disincentive for effective peer review. The reporting threshold in the statute recognized that the seriousness of

events that might be subject to peer review would vary. If the threshold is too low, it may include events that are not really useful as potential indicators of a problem. Peer review creates tension. Reporting to the NPDB increases that tension. The NPDB is still only an adjunct to a hospital's credentialing process. Hospitals and others are not limited by what is available in the NPDB. The normal screening process and rigorous follow-up are the foundation for credentialing decisions.

Instead of expanding the number of reportable events, the AHA would encourage greater protection for the kind of intensive review and follow-up that can best be accomplished without fear of someone's name being published in the NPDB. The AHA and its members are committed to demonstrating the accountability of hospitals to their communities. Implementation of an effective peer review process is the responsibility of the hospital board, leadership, and medical staff. The peer review process can always be strengthened. Training for medical staff and others who participate is an important factor. Recently, the Joint Commission on Accreditation of Health Care Organizations (JCAHO) issued guidelines for an effective peer review process. JCAHO will be assessing compliance with those guidelines. Strengthening the peer review process in turn strengthens the foundation of NPDB.

3. Should there be additional sanctions for noncompliance?

The AHA is not aware of any evidence suggesting that noncompliance with reporting requirements has risen to a level that merits either legislative or regulatory action. Again, focusing on penalties is a punitive approach. Individual instances of noncompliance should be dealt with through the current enforcement process. Sanctions already are available to the Secretary. We are not aware of any data indicating these tools are ineffective.

4. Has AHA assessed hospitals' current level of compliance with the NPDB reporting requirements?

The AHA has not conducted any studies of hospital compliance with the NPDB requirements. But, the intense interest and concern of our members about data confidentiality indicates that reports are being made, with great reliance on the confidentiality protection.

5. What has the AHA done to inform members of their reporting obligations?

At the creation of the NPDB, and in its early implementation, the AHA educated its members about the law and its requirements. Since that time, we have provided updates as new developments occurred, e.g. the 1998 proposed regulation.

6. Are hospitals querying the NPDB before hiring a practitioner?

The NPDB is actively used by hospitals. Hospitals take seriously their legal obligation to query, and to use the information as part of their credentialing process. The AHA is not aware of any evidence that hospitals are not meeting their querying obligation.

7. Is there a need for additional sanctions for failure to query the data bank?

We do not believe additional sanctions are needed. Again, since there is no evidence that hospitals are not complying, and no information which indicates that use of the existing enforcement process and sanctions is ineffective, why impose additional sanctions?

8. What has the AHA done to assess the current compliance of hospitals with their querying obligations?

In the absence of any compelling evidence of noncompliance, the AHA has not surveyed hospital compliance with NPDB querying obligations. Our information is anecdotal.

9. What has the AHA done to inform members of their querying obligations?

(Same as response to question 5.)

10. How might the AHA improve its efforts to inform members about their NPDB obligations?

We believe that hospitals are very aware of their NPDB obligations. In contrast to other areas, where the statute or regulations are ambiguous, the NPDB provisions are explicit about what is required. The AHA continues to provide information to the members as developments occur. The AHA web page and weekly newspaper are the primary vehicle for getting this type of information out to the hospitals.

11. Should information on criminal convictions be added to the NPDB?

It is our understanding that this type of information can be obtained as a matter of public record. Only the occasional media report covering an exceptional situation suggests that inclusion of this type of information would be beneficial.

12. If criminal convictions were added, should that information be available to the public through the NPDB or another means?

As mentioned above, criminal convictions are already a matter of public record. If a decision were made to make this information available to the public it does not need to be disseminated by the NPDB.

13. Should hospitals be required to query regarding residents and interns?

We assume that, in practically every circumstance, a resident is coming directly from medical school. The resident would not have any prior experience that might be the subject of a report to the NPDB. The normal screening process would be sufficient to elicit background information and pursue further inquiries if necessary. Regarding interns, most of those programs have been folded into residencies. There would be even less likelihood of reports on interns in the NPDB than on residents.

14. Should information relating to disciplinary actions be made available to the public?

Public disclosure would breach the promise of confidentiality under which the NPDB was created and the reports are being submitted. Public disclosure would not provide sufficient benefit to the consumer to outweigh the likely adverse effect on peer review.

Since its inception, there has been concern that information reported to the NPDB under the promise of confidentiality would be disclosed. The normal tensions created by peer review would be significantly heightened if reports were available to the public. Since reporting is mandatory, and the NPDB itself indicates that the information should only be used by agencies and institutions as a supplement to the primary credentialing process and as a possible indication that there is a problem, public disclosure of this information would not be appropriate. The NPDB's primary purpose is to serve as a "flagging" system for health care facilities, licensing boards, and professional societies. The purpose is to "alert" these agencies to the possibility of incompetent/dangerous performance by a health care practitioner.

If disclosure of this information were contemplated, it would immediately raise the question about access to other related information to explain or help evaluate the situation. Simply knowing that a disciplinary action occurred is not sufficient to evaluate its significance. This would potentially involve all other aspects of the practitioner's performance that are used in the credentialing process. This would seriously compromise the rights of an individual as well as the individual's privacy. It also bypasses the obligation and responsibility of the agency or health care institution to

critically review these factors when granting credentials and privileges to a practitioner. Hospitals and others who currently have access are expected to consider the report in the context of other information that can be obtained.

Also, decisions will be made on an individual basis, and may be challenged and changed. There may be inconsistency with medical board decisions. All of these are recognized and anticipated in a hospital credentialing process. In isolation, the reports in the NPDB do not provide sufficient information to determine whether a performance problem exists.

We understand that in some states there is public access to certain types of information regarding adverse actions of a licensing board. We are not familiar enough with those situations to comment on their experiences.

The AHA recognizes that consumers have a legitimate interest in knowing that the practitioners and others from whom they receive care are professionally competent. Opening the NPDB, however, is not the best way to respond to that concern.

15. Should information on malpractice payments be available to the public?

There is a significant distinction between malpractice payments made in settlement of litigation and those payments made in satisfaction of a judgment or jury verdict. As with disciplinary actions, reports of settlements would, at most, serve as notice of possible performance problems. The NPDB statute itself argues against public disclosure of settlement reports. It cautions that settlement of a malpractice claim should not be interpreted to mean that malpractice occurred. For a consumer trying to evaluate a potential caregiver, knowing only that a settlement occurred would be misleading. A consumer's decision based on a settlement report could have serious adverse consequences for a practitioner.

As presently structured, the data bank does not differentiate between payments made in situations involving substandard care and payments made for a variety of reasons, e.g. to eliminate defense of a frivolous or nonmeritorious claim, or to minimize the cost of litigation. There is no minimum threshold for reporting amounts paid in relation to malpractice claims or litigation. It is also the case that settlements are usually entered into with confidentiality provisions. It would raise serious concerns if these agreements were superceded by NPDB requirements. We understand that some of this information is available in several states. We are not currently familiar enough with those experiences to comment on how they work.

16. Would the public support release of information reported to the NPDB?

The AHA cannot speak for the general public. We believe there are legitimate and competing interests involved in balancing accountability and confidentiality. We question whether the NPDB is the most appropriate vehicle for resolving that issue.

Hospitals are committed to the delivery of high quality care to communities across the country. One important tool for the assurance of quality care for consumers is effective peer review. Instead of narrowing the confidentiality protection, there is a need for adequate and uniform protections for peer review activity across the country, to foster and enable the kind of quality reviews that are essential to the delivery of high quality care. Coupled with adequate confidentiality protections, a nonpunitive environment can be created that fosters the tough questions and hard assessments that lead to real improvement.

We hope this response addresses your concerns. We will be pleased to provide any additional information regarding the NPDB at your request.

Sincerely,

Dick Davidson

President

The Honorable John D. Dingell, Ranking Member cc:

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The Honorable Fred Upton, Chairman, Subcommittee on Oversight and Investigations

The Honorable Ron Klink, Ranking Member, Subcommittee on Oversight and **Investigations**